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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/908,994	07/17/2001	John Shigeura	4470	8729

20995 7590 10/12/2006

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EXAMINER
SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/908,994	SHIGEURA ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Withdrawal of Finality

1. The finality of the prior Office action is hereby withdrawn. Prosecution on the merits is reopened.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 10-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,593,838 (Zanzucchi et al.) in view of US Patent 5,607,646 (Okano et al.) and US Patent 5,962,228 (Brenner).

6. For convenience, claim 10 is reproduced below.

10. **(Currently amended)** A method for isolating one or more different-sequence polynucleotides from a mixture, the method comprising:

(a) flowing the mixture through a flow path containing a plurality of solid supports which are located in series in the flow path, such that the mixture flows serially through each of the plurality of solid supports, each support having bound thereto a sequence-specific capture agent complementary to a different-sequence polynucleotide, under conditions effective to specifically bind different-sequence polynucleotides to corresponding sequence-specific capture agents on one or more of the supports;,

(b) after said specific binding, releasing bound polynucleotides from a selected support by altering a physical property of that support while leaving unaltered the same physical property of at least one other of the supports; and

(c) eluting the released polynucleotides through the flow path such that the eluted polynucleotides can be isolated in separated form.

11. **(Original)** The method of claim 10, wherein the physical property is temperature.

12. **(Original)** The method of claim 11, wherein said releasing is accomplished by heating a first solid support while the temperatures of the other supports in the plurality of supports remain unchanged, such that polynucleotides are specifically eluted from the first solid support and are isolated in separated form.

7. For purposes of examination claim 10 has been interpreted as encompassing the isolation of from one to an infinite number of nucleic acid sequences, and that at a minimum, two different capture moieties are to be present and are bound at two different locations on a support

that can virtually any shape but can act as a flow path for a mixture of nucleic acids capable of flowing.

8. Zanzucchi et al., disclose a method of isolating one or more different-sequence polynucleotides from a mixture. At column 2, bridging to column 3, Zanzucchi et al., disclose using an array of wells in serial fluid connection, through which a sample is caused to pass.

9. Zanzucchi et al., column 5, fourth paragraph, teaches that the device may comprise thin film transistors so to provide power to the wells vi a leads and electrodes.

10. Zanzucchi et al., column 8, teaches that beads can be placed in one or more of the wells, and that the beads can have bound to their surface DNA material, e.g., probe or capture sequences.

11. Zanzucchi et al., column 2, teach explicitly of using the device to generate PCR fragments that can be subject to an assay/analysis.

12. Zanzucchi et al., column 10, fourth paragraph, teach that all of the wells in each module are connected together via one or more channels. Accordingly, one can cause the sample mixture to flow in a serial manner through each of the plurality of solid supports.

13. Zanzucchi et al., does not teach that the polynucleotides are released through the manipulation of physical properties such as heat and voltage potential

14. Okano et al., column 2, second and fifth paragraphs, teaches:

> It is an objective of the present invention to provide a polynucleotide capturing chip capable of simultaneously capturing a plurality of target polynucleotides, to provide a method for detecting a plurality of polynucleotides using the same and to provide a method for separating a plurality of target polynucleotides
>
> [E]ach cell of the polynucleotide capturing chip to be used as the polynucleotide capturing support also functions as an electrode for eluting the target polynucleotides, wherein the electric

fields applied to such electrodes each with a plurality of immobilized probes can be switched over one by one to elute and separate a plurality of the target polynucleotides.

Okano et al., column 3, third paragraph, teaches:

The target polynucleotides captured onto the chip via a hybridization reaction are readily eluted via heating and the like. . . If the electric field applied to the cell is switched to negative, the target polynucleotide is eluted via electrostatic repulsion.

15. Zanzucchi et al., and Okano et al., do not teach of a "plurality of solid supports." Rather, they teach of arrays that are fashioned from a single support.

16. Brenner, column 15, teaches that an array can be fashioned from a plurality of microparticles that are brought into contact with a support. And that the microparticles may comprise tag complements.

17. In view of the teachings of the prior art of record, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the microparticles of Brenner in the array of Zanzucchi et al., whereby the device would be used in a polynucleotide assay whereby specific binding reactions can take place at selected supports and eluted from same, and that the mixture would flow in a serial fashion through each of the solid supports. In view of the well-developed state of the art, said ordinary artisan would have had a most reasonable expectation of success. Therefore, and in the absence of convincing evidence to the contrary, claims 10-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,593,838 (Zanzucchi et al.) in view of US Patent 5,607,646 (Okano et al.) and US Patent 5,962,228 (Brenner).

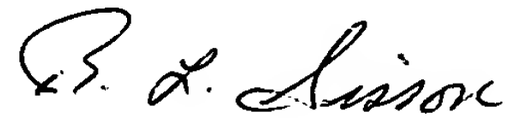
Conclusion

18. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS